

Remarks

Applicant respectfully notes the following: claims 10-12 have been rejected by the current office action but are dependent claims that depend from and further limit allowed independent claim 9; claim 20 is listed as objected to for depending from a rejected base claim but also depends from allowed claim 9; claim 119 was listed as allowed in the current office action summary but is rejected on p. 2 of the current office action; claim 119 is also a dependent claim, depending from and further limiting allowed independent claim 114; claim 111 was listed as rejected in the current office action but was actually cancelled in the previous office action response dated May 19, 2003. Applicant respectfully submits that these were clerical errors and assumes that claim 10-12, 20 and 119 are in fact allowed while claim 111 remains cancelled.

In light of the foregoing, claims 1-44, 56-61, 64-67, 69-76, 81-96, 101-103, 106-110 and 112-120 are pending. Applicant notes with appreciation the allowance of claims 1-44, 69, 75-76, 85-92, 106-110, 112-119.

Claims 56, 66-67, 70-71, 74, 81-84, 101-104 and 120 have been amended.

Claims 51-54, 62-63, 68, 77-80 and 104-105 have been cancelled.

Reconsideration of this application is respectfully requested in light of the foregoing amendments and the following remarks.

Objections to the claims

Claim 81 has been objected to as depending from rejected base claim 80. Claim 81 has been amended into independent form including the limitations of the base claim 80. The original base claim 80 has been cancelled. Dependent claims 82-84 and 120 have been amended to depend from and further limit now allowable claim 81. Therefore, Applicant respectfully submits that claims 81-84 and 120 are in condition for allowance.

Rejections under 35 U.S.C. § 102

According to MPEP § 2131, to anticipate a claim, “[t]he identical invention must be shown in as complete detail as is contained in the ... claim”. Therefore, each reference used to sustain a rejection must disclose all of the elements of the rejected claim.

Claims 52-54 and 56-63

Claims 52-54 and 56-63 stand rejected under 35 U.S.C. §102(b) as being anticipated by Büttner-Janz et al. (U.S. Patent No. 5,401,269).

Claims 52-54

Claims 52-54 have been cancelled.

Claims 56-58

Claim 56 has been amended to recite “an upper shoulder ... recessed into a portion of the perimeter of the upper contact surface and a lower shoulder ... recessed into a portion of the perimeter of the lower contact surface”. As stated previously, MPEP § 2131 requires that to sustain a rejection of claim 56, the Büttner-Janz ‘269 patent must teach or suggest each element of the claim. Büttner-Janz ‘269 does not teach or suggest “an upper shoulder ... recessed ... into a portion of the perimeter of the upper contact surface and a lower shoulder ... recessed into a portion of the perimeter of the lower contact surface.” Rather, Büttner-Janz teaches away from the use of a recessed shoulder in the central body by specifying the use of a “collar” (col. 3, line 48 through col. 4, line 37). The collar 7 of the Büttner-Janz ‘269 patent is collateral to the nominal contact surface of the central body.³ whereas claim 56 now recites that the shoulders are recessed *into* the contact surfaces themselves.

The rejection of claim 56, as amended, is no longer supported by the Büttner-Janz '269 patent. Accordingly, claim 56 should be allowed. Claims 57-58 depend from and further limit claim 56 and should also be allowed.

Claims 59-61

As stated previously, MPEP § 2131 requires that to sustain a rejection of claim 56, the Büttner-Janz '269 patent must teach or suggest each element of the claim. However, Büttner-Janz '269 does not teach or suggest "an encapsulated central body." The Büttner-Janz '269 patent teaches upper and lower shells 1 and 2 in contact with a central body 3 but the upper and lower shells leave the perimeter of the central body 3 exposed and thus the central body is not encapsulated.

Therefore, the rejection of claim 59 is not supported by the Büttner-Janz '269 patent and should be withdrawn. Claims 60-61 depend from and further limit claim 59 and should also be allowed.

Claims 62-63

Claims 62-63 have been cancelled.

Claim 74

Claim 74 stands rejected under 35 U.S.C. §102(b) as being anticipated by Ray et al. (U.S. Patent No. 6,123,465).

As stated previously, MPEP § 2131 requires that to sustain a rejection of claim 74, the Ray et al. '465 patent must teach or suggest each element of the claim. Applicant respectfully submits that in light of the amendment to claim 74, the Ray et al. '465 patent does not teach or suggest each element of the claim. The Ray et al. '465 patent fails to teach the use of "at least one sealable opening for the introduction of lubricant." Instead, the Ray et al. '465 patent teaches away from use of sealable openings by the use of a woven constraining jacket 24 with a plurality

of small openings 36 that allow body fluids to interact with the device core 22 (col. 7, lines 44-50).

Therefore, the rejection of claim 74 is not supported by the Ray et al. '465 patent and should be withdrawn.

Claims 77-79

Claims 77-79 have been cancelled.

Rejections under 35 U.S.C. §103

As provided in MPEP § 2143, “[t]o establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations.” Furthermore, under MPEP § 2142, “[i]f the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.”

Claims 64-65

Claims 64-65 stand rejected over the combination of Büttner-Janz et al. (U.S. Patent No. 5,401,269) and Walker (U.S. Patent No. 4,193,139) Applicant respectfully traverses this rejection on the grounds that these references are defective in establishing a prima facie case of obviousness with respect to claims 64-65.

It is submitted that, in the present case, the Office Action cannot factually support a prima facie case of obviousness for the following reasons.

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

The Büttner-Janz et al. '296 and Walker '139 patents cannot be applied to reject claim 64 under 35 U.S.C. § 103 which provides:

A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. (Emphasis added)

Thus, as provided in MPEP § 2143, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, neither of the cited references teaches or suggests a “shell [with a] machined inner surface,” as is claimed in claim 64. Although the Büttner-Janz et al. ‘296 teaches use of shells and a central body, the Walker ‘139 patent teaches the polishing of an *arcuate bearing surface* 25 attached to stem 21 (col. 3, lines 55-61).

Therefore, it is impossible to render the subject matter of claim 64 as a whole obvious in light of the cited references; the explicit terms of the statute cannot be met. For this reason alone, the rejection of claim 64 under 35 U.S.C. § 103 should be withdrawn. Claim 65 depends from and further limits claim 64 and should also be allowed.

2. Prior Art That Teaches Away From the Claimed Invention Cannot be Used to Establish Obviousness

Walker ‘139 patent teaches that the “[a]rcuate bearing surface 25 is polished smooth.” Polishing a component of the Walker ‘139 patent that can become exposed to the tissues of the body (as when the joint bends) clearly teaches away from claim 64, which teaches that “each shell has a machined *inner* surface,” (emphasis added).

Since it is well recognized that teaching away from the claimed invention is a per se demonstration of lack of prima facie obviousness, it is clear that the Examiner has not borne the initial burden of factually supporting any prima facie conclusion of obviousness.

Thus, for this reason alone, the rejection of claim 64 under 35 U.S.C. § 103 should be withdrawn. Claim 65 depends from and further limits claim 64 and should also be allowed.

3. The Combination of References is Improper

Assuming, arguendo, that none of the above arguments for non-obviousness apply (which is clearly not the case based on the above), there is still another compelling reason that the above-cited patents cannot be applied to reject claim 64 under 35 U.S.C. § 103.

§ 2142 of the MPEP provides:

[T]he examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made. . . . the examiner must then make a determination whether the claimed invention 'as a whole' would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination

Here, neither of the cited references teaches, or even suggests, the desirability of the combination since neither teaches a shell with a machined inner surface as in claim 64.

Thus, it is clear that neither of the cited patents provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

In this context, the MPEP further provides in §2143.01:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (Emphasis added)

In the above context, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In this case, the Examiner has admitted the use of hindsight, justified by the argument that "any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning." *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The Applicant respectfully disagrees and argues that under the current standards, the Federal Circuit has forbidden any use of hindsight: "This court *forbids the use of hindsight* in the selection of references that comprise the case of obviousness." *In re Rouffet*, 47 USPQ 2d 1453, 1458 (Fed. Cir. 1998)(emphasis added). Thus, it is respectfully submitted that the Examiner has used an R-56961v2

outdated and impermissible standard to justify the use of hindsight.

Therefore, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 64 under 35 U.S.C. § 103 should be withdrawn. Claim 65 depends from and further limits claim 64 and should also be allowed.

Claims 66-68 and 70-73

Claims 66-68 and 70-73 stand rejected over the combination of Büttner-Janz et al. (U.S. Patent No. 5,401,269) and Ducheyne et al. (U.S. Patent No. 4,990,163).

Claims 66-67

Claims 66-67 have been amended to depend from and further limit allowable claim 41 and should therefore be allowable for at least this reason.

Claim 68

Claim 68 has been cancelled.

Claims 70-71

Claims 70-71 have been cancelled.

Claim 72

Applicant respectfully traverses the U.S.C. § 103 rejection on the grounds that the cited references are defective in establishing a prima facie case of obviousness with respect to claim 72 for the following independent reasons:

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

As provided in MPEP § 2143, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. The Büttner-Janz et al. '269 patent teaches upper and

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lower plates with top surfaces that contact the vertebrae being “provided with teeth 5 which penetrate into the vertebrae...” (col. 2, line 63 through col. 3, line 2). However, neither of the cited references teaches or suggests a “shell [with a] rough outer surface that is *not teeth-shaped*,” (emphasis added), as is claimed in claim 72.

Therefore, it is impossible to render the subject matter of claim 72 as a whole obvious in light of the cited references; the explicit terms of the statute cannot be met. For this reason alone, the rejection of claim 72 under 35 U.S.C. § 103 should be withdrawn.

2. The Combination of References is Improper

As stated before, contrary to the requirements of MPEP §2143.01 and court holdings as set forth previously, it is clear that in the present case, the combination arises solely from impermissible hindsight based on the invention itself without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 72.

Therefore, the Examiner’s burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 72 under 35 U.S.C. § 103 should be withdrawn.

Claim 73

Applicant respectfully traverses the U.S.C. § 103 rejection on the grounds that the cited references are defective in establishing a prima facie case of obviousness with respect to claim 73 for the following independent reasons:

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

As provided in MPEP § 2143, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. The Büttner-Janz et al. ‘269 patent teaches the use of “teeth” to anchor a prosthesis to a vertebrae, (col. 2, line 63 through col. 3, line 2). The Ducheyne et al. ‘163 patent teaches materials and processes to promote bone *ingrowth* to achieve

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prosthetic fixation, (col. 4, lines 25-32, col. 6, lines 15-18). However, neither of the cited references teaches or suggests a “shell [that] has an outer surface that is coated to provide *friction* between the outer surface and bone,” (emphasis added), as is claimed in claim 73.

Therefore, it is impossible to render the subject matter of claim 73 as a whole obvious in light of the cited references; the explicit terms of the statute cannot be met. For this reason alone, the rejection of claim 73 under 35 U.S.C. § 103 should be withdrawn.

2. Prior Art That Teaches Away From the Claimed Invention Cannot be Used to Establish Obviousness

The Ducheyne et. al. ‘163 patent teaches a method of depositing a coating on implantable prostheses to promote bony ingrowth, (Ducheyne et al. ‘163 Abstract). This clearly teaches away from claim 73 which recites a “shell [that] has an outer surface that is coated to provide *friction* between the outer surface and bone,” (emphasis added).

Since it is well recognized that teaching away from the claimed invention is a per se demonstration of lack of prima facie obviousness, it is clear that the Examiner has not borne the initial burden of factually supporting any prima facie conclusion of obviousness.

Thus, for this reason alone, the rejection of claim 73 under 35 U.S.C. § 103 should be withdrawn.

2. The Combination of References is Improper

As stated before, contrary to the requirements of MPEP §2143.01 and court holdings as set forth previously, it is clear that in the present case, the combination arises solely from impermissible hindsight based on the invention itself without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 73.

Therefore, the Examiner’s burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 73 under 35 U.S.C. § 103 should be withdrawn.

Claims 93-96 and 101-103

Claims 93-96 and 101-103 stand rejected over the combination of Bryan et al. (U.S. Patent No. 5,674,296) and Buechel et al. (U.S. Patent No. 5,868,796).

Claims 93-96

Applicant respectfully traverses the U.S.C. § 103 rejection on the grounds that the references are defective in establishing a prima facie case of obviousness with respect to claims 93-96 for the following independent reasons:

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

As provided in MPEP § 2143, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. The Buechel et al. '796 patent teaches a coating 26 applied to the outer surfaces of the prosthesis 20. However, it does not teach or suggests a "central body [that] is *impregnated* with a surface hardening substance," (emphasis added), as is claimed in claims 93-94. Nor does the Buechel et al. '796 patent teach or suggest a "central body [that] is *impregnated* with a surface lubricity increasing material," (emphasis added) as is claimed in claims 95-96.

Therefore, it is impossible to render the subject matter of claim 73 as a whole obvious in light of the cited references; the explicit terms of the statute cannot be met. For this reason alone, the rejection of claims 93-96 under 35 U.S.C. § 103 should be withdrawn.

2. Prior Art That Teaches Away From the Claimed Invention Cannot be Used to Establish Obviousness

The Buechel et al. '796 patent teaches a method of depositing a coating on an implantable prostheses that promotes wear resistance and lubricity (col. 8, lines 24-28). This clearly teaches away from claims 93-96 which recite a "central body [that] is *impregnated*," (emphasis added), in order to promote wear resistance and lubricity.

Since it is well recognized that teaching away from the claimed invention is a per se demonstration of lack of prima facie obviousness, it is clear that the Examiner has not borne the initial burden of factually supporting any prima facie conclusion of obviousness.

Thus, for this reason alone, the rejection of claim 93-96 under 35 U.S.C. § 103 should be withdrawn.

3. The Combination of References is Improper

As stated before, contrary to the requirements of MPEP §2143.01 and court holdings as set forth previously, it is clear that in the present case, the combination arises solely from impermissible hindsight based on the invention itself without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 93-96.

Therefore, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 93-96 under 35 U.S.C. § 103 should be withdrawn.

Claims 101 and 103

Claims 101 and 103 have been amended. In light of the amendments, Applicant respectfully submits that the cited references do not support prima facie case of obviousness as to claims 101-103 and should be withdrawn for the following independent reasons

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

As provided in MPEP § 2143, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, neither of the cited references teaches or suggests a "an elastomeric central body having a coating thereon," as is claimed in claims 101-103. Rather, the Buechel et al. '796 patent teaches a coating 26 applied to the end 17 of a metal surfaces 16 (col. 7 lines 41-43).

Therefore, it is impossible to render the subject matter of claims 101-103 as a whole obvious in light of the cited references; the explicit terms of the statute cannot be met. For this reason alone, the rejection of claims 101 and 103 under 35 U.S.C. § 103 should be withdrawn.

2. Prior Art That Teaches Away From the Claimed Invention Cannot be Used to Establish Obviousness

The Buechel et al. '796 patent teaches a method of depositing a coating 26 on a solid portion of an implantable prostheses 20 to promote wear resistance and lubricity (col. 8, lines 24-28). This clearly teaches away from claims 101 and 103 which recite a "an elastomeric central body having a coating thereon."

Since it is well recognized that teaching away from the claimed invention is a per se demonstration of lack of prima facie obviousness, it is clear that the Examiner has not borne the initial burden of factually supporting any prima facie conclusion of obviousness.

Thus, for this reason alone, the rejection of claims 101 and 103 under 35 U.S.C. § 103 should be withdrawn.

3. The Combination of References is Improper

As stated before, contrary to the requirements of MPEP §2143.01 and court holdings as set forth previously, it is clear that in the present case, the combination arises solely from impermissible hindsight based on the invention itself without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 101 and 103.

Therefore, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 101 and 103 under 35 U.S.C. § 103 should be withdrawn.

Claim 102

Claim 102 has been amended to reflect the new limitations of claim 101 from which it depends. Claim 101 now being in condition for allowance and claim 102 depending from and further limiting claim 101, Applicant respectfully submits that claim 102 is in condition for allowance for at least this reason.

Claims 104-105

Claims 104-105 have been cancelled.

Conclusion

As a result of the foregoing, it is respectfully asserted that pending claims 1-44, 56-61, 64-67, 69-76, 81-96, 101-110 and 112-120 are in condition for allowance. Should the Examiner deem that any further amendment is desirable to place this application in condition for allowance, the Examiner is invited to contact the undersigned at the below listed telephone number. Also, Deposit Account No. 08-1394 may be used for any over or under payments.

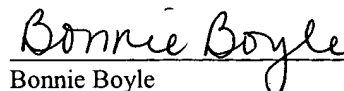
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